UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,329	08/21/2001	Luc Desgroseillers	163-34	8479

23117 7590 10/21/2003

NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 10/21/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,329	DESGROSEILLERS ET AL.	
	Examiner	Art Unit	
	Yong D Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *1-5,7-13,15-28 and 30-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,14,29,39 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 August 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed on August 18, 2003, amending claims 6, 14 and 29 and adding claims 39-40.

Claims 1-40 are pending.

Election/Restrictions

Applicant's election without traverse of Group III in Paper No. 16 is acknowledged. Applicants are correct in noting that the claims listed in Groups XV to XX were erroneous. Group XV is drawn to claims 30-31, Group XVII is drawn to claim 32, Group XVIII is drawn to claim 33, Group XIX is drawn to claims 34-37 and Group XV is drawn to claim 38.

Claims 1-5, 7-13, 15-28 and 30-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 16.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on December 4, 2001 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

The sequences in Figure 1-6 should be identified by SEQ ID numbers and must comply with the Sequence Rules, see 37 CFR 1.821-1.825.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 14 is drawn to a vector comprising a polynucleotides having 80% sequence identity with the N-terminal domain of SEQ ID NO:13 with no limitations to the function of the encoded polypeptide. Therefore, this claim is drawn to a large variable genus of polynucleotides having unknown activity or inactive variants. Applicants only

describe the NEP of SEQ ID NO:13. The specification does not describe the function of all the polypeptide sequences derived or modified from SEQ ID NO:13 and therefore, many functionally unrelated polynucleotides are encompassed within the scope of these claims. Therefore, applicants fail to describe representative species by identifying characteristics or structural properties other than having 80% homology to the N-terminal domain of SEQ ID NO:13.

Claim 29 is drawn to a recombinant host cell expressing any protein, polypeptide or variants thereof that manage a disease, physiological process or pain. Therefore, the claims are drawn to a host cell expressing a genus of polypeptides capable of managing a wide variety of diseases, physiological process or pain. The specification does not describe host cell expressing all polypeptides that manage a disease, physiological process or pain.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 14 and 29.

Claims 14 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotides encoding the NEP protein of SEQ ID NO:13 and host cell comprising said polynucleotide, does not reasonably provide enablement for a host cell comprising any polynucleotides or a vector comprising a polynucleotides encoding a polypeptide having unknown function. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The function of a polypeptide can not be predicted from its structure and the specification does not teach how to use polypeptides with unknown function. Therefore, the breadth of these claims is much larger than the scope enabled by the specification.

While recombinant techniques are available, it is not routine in the art to screen large numbers of amino acids where the expectation of obtaining similar sequences is unpredictable. The amino acid sequence determines the structural and functional properties of an enzyme. Knowledge of which sequences can be altered or removed and still result in similar protein activity is well outside the realm of routine experimentation.

The specification, which places no limitation on the structure of the polypeptides as discussed above, does not support the broad scope of the claims because the specification does **not** establish: (A) regions of the NEP structure which may be

modified without effecting its activity; (B) the general tolerance of to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

The specification also does not teach host cell expressing all polypeptides that manage a disease, physiological process or pain. Even though many polypeptides that manage a disease, physiological process or pain are known in the art, the instant claims encompass any polypeptides. The specification lacks teachings of all polypeptides and therefore lacks sufficient teachings covering all polypeptides that manage a disease, physiological process or pain.

Therefore, one of ordinary skill would require guidance in order to make polynucleotides having unknown function and use host cells comprising any polypeptides in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 39-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 in confusing because a polynucleotide that is complementary to SEQ ID NO: 12 cannot encode a polypeptide having NEP activity.

In claims 6 and 39-40, the exact hybridization condition is unclear. Different nucleic acids hybridize to a DNA sequence under different conditions. Therefore, the scope of DNA molecules in claims 6 and 39-40 are unclear.

Claims 6 and 39-40 are confusing because either a polypeptide has NEP metalloprotease activity or it does not. The meaning of the phrase "NEP-like" is unclear.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Marra et al.

Marra et al. (form PTO-892) teach a polynucleotide that hybridizes to SEQ ID NO:12 under high stringency. Marra et al. also teach a vector comprising said polynucleotide. Therefore, the teaching of Marra et al. anticipates claims 6 and 39.

Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Bandman et al.

Bandman et al. (U.S. Patent No. 5,817,482 – form PTO-892) teach a host cell expressing a protein that manages a disease, physiological process or pain (abstract). Therefore, the teaching of Bandman et al. anticipates claim 29.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong D. Pak
Patent Examiner

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

October 16, 2003